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Judith C. Moorad
Vice President - Safety, Health & Environment

EQUIVA SERVICES LLC
Shell, Texaco & Saudi Aramco Working Together

8EHQ-0102-15068

January 25, 2002

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2002 JAN 30 AM 8:3

TS 7404, Document Control Officer
(Attn: TSCA Section 8(e) Coordinator)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue N.W.
Washington, D.C. 20460

Contain NO CBI

8EHQ-02-15068

Re: TSCA 8(e) Submission

Dear Sir/Madam:

Equiva Services LLC (Equiva) provides Product Stewardship services to Equilon Enterprises LLC (Equilon) and Motiva Enterprises LLC (Motiva). Equilon and Motiva are participating in an industry consortium conducting testing of various fuels and fuel oxygenates pursuant to Section 211(b) requirements of the Clean Air Act. Equiva is submitting this TSCA 8(e) notification on the behalf of Equilon and Motiva because the preliminary raw data from a developmental toxicity study includes observations that EPA may consider to be TSCA 8(e) reportable.

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The industry consortium contracted for a study that was designed to evaluate the potential, if any, for developmental toxicity in female CD-1 mice exposed by inhalation (whole-body) to vapor derived from condensate of the 10% lowest-boiling fraction of a gasoline-MTBE mixture (this vapor is hereafter referred to as the "test material").

In this study, groups of 25 dams were exposed by whole-body inhalation to target test material concentrations of 0, 2000, 10,000, or 20,000 mg/m^3 (control, low-, mid- and high-dose, respectively) for at least 6 hours/day, from days 5 - 17 of gestation. MTBE concentration measurements are not available. However by calculation target MTBE levels would be expected to have been approximately 21.5% of these target concentrations, equating to 0, 430, 2050 and 4300 mg/m^3 MTBE in the control, low, mid and high-dose groups, respectively.

The preliminary, raw data we received indicate that ectopia cordis was observed in one fetus from one litter in the low-exposure group, and two fetuses from one litter in the mid-dose group. One fetus in the same mid-dose litter exhibited gastroschisis. These conditions were not observed in any fetuses from the high-dose group or from the control group.

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12700 Northborough Drive
Houston, TX 77067-2508

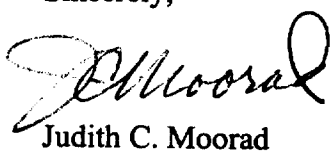
Based on our review of the raw data we note the following:

- The lack of a dose-response. These conditions were not observed in the high-dose group.
- The absence of differences among the treatment groups in number of litters, mean number of fetuses per litter, or resorption rates which might have obscured an effect in the high-dose group.
- The absence of these conditions in previous, comparable developmental toxicity testing of MTBE alone and, of low-boiling gasoline vapor condensate alone.
- The absence of any statistically significant increase in overall gross malformations or related lesser effects that would typically accompany a teratogenic insult.

In view of this, the ectopia cordis and gastroschisis observed in the raw data are most likely unrelated to exposure to the test material. However, Equiva is reporting this information on the behalf of Equilon and Motiva as a precautionary measure for EPA's review and consideration. The consortium has retained two outside expert developmental toxicologists and requested their review and interpretation of the preliminary data.

A copy of the raw data is attached for your review. The two sets of tables separately summarize external and visceral observations. RRN A101-125, A201-225, A301-325 and A401-425 refer to dams from the control, low, mid and high dose groups, respectively. We will submit the final report of the developmental toxicologists when it becomes available. In addition, EPA will receive the draft and final Section 211(b) study reports after they are completed.

Sincerely,



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Enclosures:

Summary of external data
Summary of visceral data